

## 510(k) PREMARKET NOTIFICATION

Genzyme Corporation  
One Kendall Square  
Cambridge, MA 02139

Genzyme Direct Amylase Verifier

September 15, 1999

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**510(k) Summary Of Safety and Effectiveness Information Upon Which An Equivalence  
Determination Could be Made**

**Trade or Proprietary Name:** Genzyme Direct Amylase Verifier

**Common or Usual Name:** Calibrator for the Genzyme Direct Amylase assay

**Classification Name:** Calibrator, Secondary

**Manufacturer:** Genzyme Diagnostics  
One Kendall Square  
Cambridge, MA 02139-1562

**Contact Person:** Robert Yocher, Vice President, Regulatory Affairs (617) 374-7275  
Barbara Pizza, Manager, Regulatory Affairs (617) 252-7953

The Genzyme Direct Amylase Verifier is intended to be used as a companion product with the Genzyme Direct Amylase reagent manufactured by Genzyme but sold separately. The product is buffer formulated with human amylase and preservative. The Verifier values are in the clinically relevant range of 200 U/L to 275 U/L. The Direct Amylase Verifier is for use during initiation or validation of Genzyme Direct Amylase reagent on a clinical chemistry analyzer to confirm the analyzer has the correct enzyme factor. It is possible this Verifier would need to be used again if significant maintenance was performed on the analyzer and this is addressed in the Direct Amylase Verifier product labeling.

The Genzyme Direct Amylase Verifier used with the Genzyme Direct Amylase reagent on other analyzers performs substantially equivalent to the Genzyme Direct Amylase Reagent on the Roche Cobas FARA Analyzer as demonstrated by results obtained in Genzyme's testing.

*In lieu of a 510(k) statement under 513(i) of the Act, this information is provided as a 510(k) summary for disclosure to any other persons/companies without the specific written authorization from Genzyme Corporation.*



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

OCT 4 1999

Ms. Barbara Pizza  
Manager, Regulatory Affairs  
Genzyme Corporation  
One Kendall Square  
Cambridge, Massachusetts 02139-1562

Re: K993132  
Trade Name: Genzyme Direct Amylase Verifier  
Regulatory Class: II  
Product Code: JIT  
Dated: September 15, 1999  
Received: September 20, 1999

Dear Ms. Pizza:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

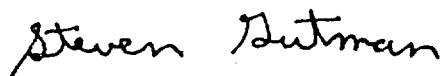
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D, M.B.A.  
Director  
Division of Clinical  
Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Abbreviated 510(k) PREMARKET NOTIFICATION

Genzyme Corporation  
One Kendall Square  
Cambridge, MA 02139

Direct Amylase Verifier

CONFIDENTIAL

September 15, 1999

3.0 INTENDED USE

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510(k) Number (if known): K 993132

Device Name: Direct Amylase Verifier

Indications for Use:

For determination of the instrument specific Direct Amylase reagent factor for analyzers using Genzyme Direct Amylase Reagent.

Jean Cooper  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K 993132

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)